

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Anita Meiklejohn Fish & Richardson 225 Franklin St. Boston MA 02110 APR 23 2008

In Re: Patent Term Extension

Application for

U.S. Patent No. 4,650,787

RE: SANVAR® (vapreotide acetate)

Dear Ms. Meiklejohn

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2009. A copy of the Federal Register notice, published on April 15, 2008 at 73 Fed. Reg. 20256, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. Till Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc:

Office of Regulatory Policy

Food and Drug Administration

10903 New Hampshire Ave., Building 51, Rom 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc.
Request for Patent Term Extension
U.S. Patent No. 4,650,787

ORDER GRANTING INTERIM EXTENSION

On March 24, 2008, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2008), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2009.

Date

Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office